



General

Guideline Title

2012 EHRA/HRS expert consensus statement on cardiac resynchronization therapy in heart failure: implant and follow-up recommendations and management.

Bibliographic Source(s)

European Heart Rhythm Association, European Society of Cardiology, Heart Rhythm Society, Heart Failure Society of America, American Society of Echocardiography, American Heart Association, European Association of Echocardiography, Heart Failure Association, Daubert JC, Saxon L, Adamson PB, Auricchio A, Berger RD, Beshai JF, Breithard O, Brignole M, Cleland J, Delurgio DB, Dickstein K, Exner DV, Gold M, Grimm RA, Hayes DL, Israel C, Leclercq C, Linde C, Lindenfeld J, Merkely B, Mont L, Murgatroyd F, Prinzen F, Saba SF, Shinbane JS, Singh J, Tang AS, Vardas PE, Wilkoff BL, Zamorano JL. 2012 EHRA/HRS expert consensus statement on cardiac resynchronization therapy in heart failure: implant and follow-up recommendations and management. Heart Rhythm. 2012 Sep;9(9):1524-76. [351 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 14, 2016 – General anesthetic and sedation drugs : The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

Recommendations

Major Recommendations

Note: Cardiac resynchronization therapy (CRT) can be administered with or without defibrillation therapy. For the purposes of this document, the term CRT applies to either a CRT pacemaker (CRT-P) or CRT-defibrillator (CRT-D). If the paragraph is relevant to only one type of therapy, the device type will be listed as CRT-P or CRT-D.

Pre-Implant Recommendations

Is Recommended

A careful evaluation of comorbidities and an estimate of life expectancy is recommended.

A thorough pre-implant history and physical examination including review of vital signs and laboratory tests is recommended.

Cardiac resynchronization therapy (CRT) candidates should have stable heart failure status on guideline-directed medical therapy prior to implant.

A pre-implant comprehensive echocardiogram for quantification of left ventricular ejection fraction (LVEF) and assessment of cardiac size and function is recommended.

A pre-implant 12-lead electrocardiogram (ECG) including QRS duration measure (120–130 ms) and characterization of QRS morphology is recommended.

In patients at high thromboembolic risk on oral anticoagulant therapy with warfarin, continuing therapy at reduced dosage with close monitoring of international normalized ratio (INR 2–3) is recommended perioperatively. Post-operative use of heparin is discouraged.

Preoperative treatment with an antibiotic that has in vitro activity against staphylococci is recommended for infection prophylaxis.

May Be Useful

Pre-implant formal functional status testing including a quality of life (QOL) measure may be useful for monitoring CRT response.

Cardiac magnetic resonance imaging (MRI) may be useful to assess cardiac function and provide detailed information about viable myocardium in distribution of a coronary sinus (CS) branch vein considered for left ventricular (LV) lead implant.

Venous anatomic mapping using computed tomography (CT) angiography may be useful in certain patient populations. These include patients with prior LV lead implant failure or those at risk for abnormal venous anatomy.

Development of a pre-implant strategy should be considered to identify and manage atrial fibrillation or frequent premature ventricular contractions (PVCs) that may impair the ability of CRT to deliver therapy continuously.

In patients at low to moderate thromboembolic risk on oral anticoagulant therapy with warfarin, continuing at reduced dosage (INR 1.5–2) or withholding therapy 3–5 days preoperatively can be useful to minimize bleeding risk.

In patients at low–moderate thromboembolic risk on direct thrombin or factor Xa inhibitor agents, withholding such therapy 2–3 days before surgery can be useful to minimize bleeding risk.

Are Not Recommended

CRT implant should be deferred in patients with acutely decompensated heart failure, who are dependent on inotropes, or who have unstable ventricular arrhythmias until their medical status is improved.

Echocardiographic dyssynchrony assessment should not be used to exclude patients from consideration for CRT.

CRT Implant Recommendations

Is Recommended

Intra-operative haemodynamic monitoring including careful attention of volume status is recommended.

The right ventricular (RV) lead is recommended as the first intracardiac lead implanted.

CS venography is recommended to create a roadmap that guides lead selection and assists with navigation.

LV lead testing is recommended to assure an adequate safety margin for capture and avoidance of phrenic nerve stimulation (PNS).

Careful discussion with patients regarding the risk and benefits of CRT-D (defibrillator) vs. CRT-P (pacemaker) device implant is recommended.

prior to the decision as to the type of CRT device implanted.

May Be Useful

General anaesthesia may be considered for CRT implants.

Controversy exists regarding the value of routine acute defibrillation testing but major CRT trials included defibrillation threshold (DFT) testing. The decision to perform DFT testing should be made on an individual basis by the treating physician.

Are Not Recommended

It is not recommended to place the LV lead in an apical position.

Pre-Discharge Evaluation Recommendations

Is Recommended

A physical examination, device interrogation, chest X-ray, and surface ECG is recommended prior to discharge.

Careful attention to volume status is recommended after the implantation procedure as an acute response to CRT may include significant diuresis.

A standard echocardiographic assessment is recommended prior to discharge if a procedural complication is suspected on the basis of patient symptoms or clinical findings.

An assessment to assure 100% biventricular capture is recommended prior to discharge.

The majority of patients implanted with CRT should remain in the hospital overnight after implant to observe clinical status.

CRT Follow-Up Recommendations

Is Recommended

A close degree of cooperation is recommended in the follow-up of the CRT recipient between the heart failure and electrophysiology follow-up physician.

A minimum in-clinic follow-up interval of 6 months is strongly recommended for CRT recipients.

Remote monitoring and follow-up in addition to in-clinic follow-up is recommended. Patients should be encouraged to initiate a remote transmission if new symptoms or concerns arise.

Follow-up visits that include a patient history, physical examination, device interrogation and testing, and systematic analysis of device data is recommended.

Optimization including upward titration of heart failure drug therapies, if appropriate, is recommended to maximize response to CRT.

Evaluation of LV function or other adjuncts to assess heart failure progression or regression is recommended during follow-up.

May Be Useful

Catheter ablation of the atrioventricular (AV) node in the setting of atrial fibrillation with native conduction can be useful if CRT is not being delivered consistently.

CRT Management Recommendations

Is Recommended

Assessment of patient response to CRT, including an evaluation of symptoms and functional response and echocardiographic measures of cardiac function, is recommended.

An assessment of potentially reversible causes for nonresponse is recommended in patients without demonstrable improvement in heart failure status after CRT implant.

A device interrogation is recommended to assess for atrial and ventricular arrhythmias, quality of CRT delivery (% effective biventricular capture) and rate response.

Optimization of medical therapy, assurance of appropriate and consistent biventricular pacing and treatment of arrhythmias is recommended.

May Be Useful

Echocardiographically directed or empiric AV or ventriculoventricular (VV) timing optimization, or LV lead repositioning may be considered in selected patients but their role in improving response has not been proven.

Discontinuation of CRT by programming off LV stimulation may be considered if there is no clear evidence of response to therapy or concern exists that LV pacing is introducing risk.

In patients who do not respond to CRT and continue to experience heart failure symptoms, alternative treatment options should be considered such as placement of a LV assist device or cardiac transplantation.

Special Considerations

Is Recommended

Pre-implant patient education including information about the need and function of the CRT device and follow-up plan is recommended. There are a variety of digital patient educational tools that can be utilized to fully inform the patient as to the risks and benefits of CRT or CRT-D therapy.

Clinical Algorithm(s)

The following are provided in the original guideline document:

- Possible decision tree for successful delivery of cardiac resynchronization therapy (CRT)
- Algorithm for echo guided candidacy for atrioventricular (AV) optimization determined from mitral inflow pattern post-cardiac resynchronization therapy (CRT) implant (adapted from American Society of Echocardiography Dyssynchrony Guidelines, 2008)

Scope

Disease/Condition(s)

Heart failure

Guideline Category

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Cardiology

Intended Users

Physicians

Guideline Objective(s)

To fill in knowledge gaps with consensus opinion where the clinical evidence is less than certain in the areas of pre-implant, implant, and post-implant management of the cardiac resynchronization therapy (CRT) recipient

Target Population

Patients with symptomatic heart failure who are considered for cardiac resynchronization therapy (CRT)

Interventions and Practices Considered

1. Pre-implant evaluation and management
 - History and physical examination, including vital signs, laboratory tests, evaluation of comorbidities, estimate of life expectancy, functional status testing, echocardiogram, electrocardiogram, cardiac magnetic resonance imaging, and venous anatomic mapping using computed tomography angiography
 - Stabilization of heart failure status
 - Continuation or withholding of warfarin therapy or direct thrombin or factor Xa inhibitor agents based on risk
 - Discouraging post-operative use of heparin
 - Preoperative antibiotic prophylaxis
 - Pre-implant strategy to identify and manage atrial fibrillation or frequent premature ventricular contractions (PVCs)
2. Cardiac resynchronization therapy (CRT) implantation evaluation and management
 - Intra-operative haemodynamic monitoring including careful attention to volume status
 - Coronary sinus (CS) venography
 - Left ventricular (LV) lead testing to assure an adequate safety margin for capture and avoidance of phrenic nerve stimulation (PNS)
 - Use of general anaesthesia
 - Acute defibrillation testing
 - Device interrogation to assess for atrial and ventricular arrhythmias, quality of CRT delivery, and rate response
 - Optimization of medical therapy, assurance of appropriate and consistent biventricular pacing and treatment of arrhythmias
 - Echocardiographically directed or empiric atrioventricular (AV) or ventriculoventricular (VV) timing optimization, or LV lead repositioning in selected patients
 - Discontinuation of CRT and alternative treatment options in patients who do not respond to CRT
3. Pre-discharge evaluation
 - Physical examination, device interrogation, chest X-ray, surface electrocardiogram (ECG), assessment of volume status, and echocardiographic assessment if a procedural complication is suspected
 - Assessment to assure 100% biventricular capture before discharge
 - Overnight hospitalization
4. Follow-up
 - Close cooperation between the heart failure and electrophysiology follow-up physician
 - Follow-up interval of 6 months, with remote monitoring and follow-up visits that include patient history, physical examination, device interrogation and testing, and systematic analysis of device data
 - Optimization including upward titration of heart failure drug therapies, if appropriate
 - Evaluation of LV function or other adjuncts
 - Catheter ablation of the AV node in the setting of atrial fibrillation with native conduction
5. Special considerations
 - Pre-implant patient education including information about the need and function of the CRT device and follow-up plan

Note: The following interventions/practices were considered but not recommended:

CRT implantation in patients with acutely decompensated heart failure, who are dependent on inotropes, or who have unstable ventricular arrhythmias

Use of echocardiographic dyssynchrony assessment to exclude patients from consideration for CRT

Placing the LV lead in an apical position

Major Outcomes Considered

- Prognostic value of pre-implant patient risk assessment
- Clinical value of diagnostic and monitoring tests
- Mortality
- Cardiac transplant
- Heart failure hospitalization
- Left ventricular (LV) volume and left ventricular ejection fraction (LVEF)
- New York Heart Association (NYHA) functional class
- Results of 6 minute walk test
- Peak volume of oxygen consumption (VO2)
- Quality of life score
- Patient global assessment
- Perioperative and postoperative complications
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Medline and PubMed databases were searched. All initial literature searches were performed at the time the document writing committee was initiated in May of 2011. Subsequent literature searches were performed as needed throughout document development and concluded in June of 2012. All randomized and observational studies in humans were included in literature searches. Initial search term of cardiac resynchronization therapy was used; each section author was responsible for adding search criteria relevant to their section.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review

Review of Published Meta-Analyses

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This document represents the efforts of a multi-disciplinary group of physicians with clinical and investigational expertise in cardiac resynchronization therapy (CRT) for treatment of heart failure. The document's recommendations summarize the writing group's consensus opinions supported by 70% or greater of the writing committee by anonymous vote.

The writing group is composed of 28 members representing seven organizations: the American Heart Association (AHA), the American Society of Echocardiography (ASE), the European Heart Rhythm Association (EHRA), the Heart Failure Association of the European Society of Cardiology (HFA), the European Association of Echocardiography (EAE) of the European Society of Cardiology, the Heart Failure Society of America (HFSA), and the Heart Rhythm Society (HRS).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

There has been great interest in and discussion around whether cardiac resynchronization therapy (CRT) is cost effective. This is due to the significant up-front cost of the devices and the limited life expectancy of patients with advanced heart failure and QRS delay.

Cost-effectiveness analysis of three clinical trials of CRT for both CRT-defibrillator (CRT-D) and CRT-pacemaker (CRT-P) devices that have medical therapy only randomization arms and measures of hospitalization and mortality as primary endpoints provides important data.

The COMPANION trial, that compared CRT-P and CRT-D therapy with optimal medical therapy, demonstrated significant improvements in the primary endpoint for both devices over a 12-month follow-up. Using quality-of-life adjusted survival analysis (QALY), assuming therapy over a 7-year follow-up interval, both devices were associated with cost effectiveness (CRT-P \$19,600; CRT-D \$43,000 QALY) compared with optimal medical therapy. This trial, performed in the USA, utilized Medicare cost data and assumed a cost-effective benchmark of \$50,000 to \$100,000 per QALY.

Additional cost-effectiveness analysis was performed using data from the UK. In this study, cost data were based on the CARE-HF trial data for CRT devices (performed largely in Europe) also utilized the COMPANION data for CRT-D devices and similarly found very favourable incremental cost-effectiveness per life year gained and per QALY gained for both devices when compared with medically treated patients over a 6- to 7-year follow-up after implantation.

Cardiac resynchronization therapy has also demonstrated to be a cost-effective intervention when applied to patients with less advanced symptom class heart failure.

Both CRT and CRT-D devices demonstrate cost-effectiveness compared with internationally accepted benchmarks for other therapies, including medical therapies when analysis is performed over the battery life of the devices. The addition of ICD therapy to the CRT device increases cost because the device is more expensive but cost-effectiveness is still within accepted standards as it has been demonstrated in the USA and Europe.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The original guideline document was approved by the European Heart Rhythm Association, a registered branch of the European Society of Cardiology (ESC), the Heart Rhythm Society, the American Heart Association, the American Society of Echocardiography, the Heart Failure Society of America, the American Heart Association Science Advisory and Coordinating Committee, the European Association of

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate evaluation, implant and management of heart failure patients considered for cardiac resynchronization therapy (CRT)

Potential Harms

- Implantation of a cardiac rhythm device including cardiac resynchronization therapy (CRT) during concomitant use of oral anticoagulants or dual antiplatelet therapy poses an increased risk of perioperative bleeding complications (i.e., pocket haematoma), whereas its discontinuation poses a thromboembolic risk.
- In a multicentre registry of 6319 consecutive recipients of pacemakers or defibrillators in 44 medical centres, device-related infections were reported in 0.68% within 12 months of implantation. Infections occurred more frequently with use of temporary pacing or other procedures before implantation, early reintervention and without antibiotic prophylaxis.
- Implanting the left ventricular (LV) lead usually involves contrast administration to define the coronary venous anatomy and to help identify and cannulate the coronary sinus (CS) ostium. Because of the high prevalence of renal dysfunction, diabetes and low blood pressure in candidates for CRT, contrast nephropathy following CRT may occur despite the modest amount of contrast media used (i.e., <1/10 of that used for coronary angiography).
- The CRT implant often takes considerably longer than other pacemaker and implanted cardioverter defibrillator (ICD) procedures, and is undertaken in a patient group at increased risk of haemodynamic compromise. The prolonged supine position predisposes to pulmonary oedema, while severe hypotension may result from intravenous sedation and opiates in a dehydrated patient.
- Since defibrillator testing carries risk (e.g., circulatory arrest) of adverse outcomes, many centres have moved away from routine testing in CRT recipients, who may be at higher risk given the severity of their LV dysfunction and heart failure.
- Some small studies demonstrated that prolongation of QT-dispersion upon CRT is associated with life-threatening arrhythmias.
- The most recognized perioperative complications are failure to successfully implant the LV lead, pocket haematoma, hemo/pneumothorax, CS dissection, cardiac perforation or tamponade, extracardiac stimulation, complete heart block, LV lead dislodgement (including loss of capture), exacerbation of heart failure, acute renal failure, and death. Overall perioperative complication rates range from 4% in more recent trials to as high as 28% in earlier CRT trials.
- Exacerbation of heart failure may occur in relatively unstable patients, in those who receive excessive intravenous fluids intraoperatively, after prolonged procedures, or as a result of defibrillation threshold (DFT) testing, anaesthetic agents, or other medical adverse reactions.
- In patients with CRT, long-term complications are more frequent than in single- or dual-chamber pacemaker/ICD systems since these patients usually have advanced heart disease, implantation is more complex, and there is more hardware, particular leads at risk. The annual risk of CRT system infection detected during follow-up averages between 1% and 3% and tends to increase over time and is associated with prolonged hospitalization stay and increased cost.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

End of Life Care

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

European Heart Rhythm Association, European Society of Cardiology, Heart Rhythm Society, Heart Failure Society of America, American Society of Echocardiography, American Heart Association, European Association of Echocardiography, Heart Failure Association, Daubert JC, Saxon L, Adamson PB, Auricchio A, Berger RD, Beshai JF, Breithard O, Brignole M, Cleland J, Delurgio DB, Dickstein K, Exner DV, Gold M, Grimm RA, Hayes DL, Israel C, Leclercq C, Linde C, Lindenfeld J, Merkely B, Mont L, Murgatroyd F, Prinzen F, Saba SF, Shinbane JS, Singh J, Tang AS, Vardas PE, Wilkoff BL, Zamorano JL. 2012 EHRA/HRS expert consensus statement on cardiac resynchronization therapy in heart failure: implant and follow-up recommendations and management. *Heart Rhythm*. 2012 Sep;9(9):1524-76. [351 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Sep

Guideline Developer(s)

European Heart Rhythm Association - Professional Association

Heart Rhythm Society - Professional Association

Source(s) of Funding

Heart Rhythm Society

Guideline Committee

Task Force

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Writing group members and peer reviewers provided disclosure statements for all relationships that could be perceived as real or potential conflicts of interest.

See Table A1 in the original guideline document for experts' industry affiliations.

See Table A2 in the original guideline document for reviewers' industry affiliations.

Guideline Endorser(s)

American Heart Association - Professional Association

American Society of Echocardiography - Professional Association

European Society of Cardiology - Medical Specialty Society

European Society of Cardiovascular Imaging - Medical Specialty Society

Heart Failure Association of the ESC - Disease Specific Society

Heart Failure Society of America, Inc - Disease Specific Society

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [Heart Rhythm Society \(HRS\) Web site](#) .

Availability of Companion Documents

The following is available:

- The HRS policy for development and endorsement of clinical guidance documents from HRS and others. Washington (DC): Heart Rhythm Society (HRS); 2009 Sep. 6 p. Available from the [Heart Rhythm Society \(HRS\) Web site](#) .

Patient Resources

The following is available:

- Cardiac resynchronization therapy. Available from the [Heart Rhythm Society Web site](#) .

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NGC Status

This NGC summary was completed by ECRI Institute on March 5, 2013. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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